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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/823,468	04/12/2004	Sanford D. Altman	OAV-103XC1	4577

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/823,468

Applicant(s)

ALTMAN, SANFORD D.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 January 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The replacement drawings 9, 10A, 10B, 10C, 10D were received on 25 January 2007. These drawings are accepted.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 11, 20, 24, 25, 28-31, 34, and 35 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,758,836 to Zawacki.

In the specification and figures, Zawacki discloses the apparatus as claimed by applicant. With regard to claims 1 and 2, Zawacki discloses a dual-lumen catheter 10 with an inner lumen 30 in coaxial relationship with an outer lumen 20, wherein each lumen is formed by an independent tube with an inner surface, outer surface, distal end, and proximal end (see column 3, lines 24-45, FIG 1). Both inner lumen 30 and outer lumen 20 have open ends 38, 28 to allow fluid passage, corresponding to applicant's claimed apertures. Zawacki illustrates that the inner lumen is slideable and may extend beyond the distal end of the outer lumen (see FIGS 2, 3). Zawacki further discloses that

in certain situations, the inner lumen may be used as an arterial lumen while the outer lumen is used as the venous lumen, meeting the limitations of the claim (see column 4, lines 5-18, column 6, lines 5-24).

With regard to claims 11 and 20, Zawacki discloses that the catheter lumens may comprise a circle-C or double-D configuration (see column 4, lines 45-48).

With regard to claims 24 and 25, Zawacki illustrates that both the inner and outer lumens, 30, 20/24, comprise a plurality of circular apertures 36, 26 (see FIG 1).

With regard to claim 27, Zawacki discloses that the catheter may be made of thermoplastics such as PTFE (see column 3, lines 24-33).

With regard to claim 28, Zawacki discloses that reinforcing substances to reduce kinking may be used in the construction of the catheter, including wire (which is a metal formed as a flexible thread), which meets applicant's claim drawn to a metal (see column 4, lines 34-38).

With regard to claim 29, Zawacki discloses that the catheter assembly 10 comprises a hollow hub 40 that connects to the assembly (see FIG 1, column 3, lines 48-67). Zawacki further discloses that the inner lumen—which may act as either the venous lumen or arterial lumen, depending on the operation of the catheter see column 4, lines 5-18—is removable and replaceable (see column 1, lines 61-67).

With regard to claim 30, applicant claims the intended placement of the catheter in a patient's vasculature. Such limitations are considered by the examiner to be a statement of the intended use of the catheter. It has been held that a recitation with respect to the manner in which a claimed is intended to be employed does not

differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Zawacki specifically discloses that his catheter is designed to be employed in a patient's vasculature at the junction of the right atrium and the vena cava, and that the lumens are adjustable in order to be deployed in the right position (see column 3, lines 10-15, column 1, lines 50-60). Zawacki's disclosure indicates that the claimed catheter is capable of being placed in the location claimed by applicant, thereby meeting the limitations of the claim.

With regard to claims 31, Zawacki discloses the method claimed by applicant. Zawacki discloses providing the claimed catheter, inserting it into a venotomy site (see column 3, lines 7-22, column 9, lines 8-10), and using the catheter to remove blood, treat the removed blood, and return treated blood to the patient (see column 1, lines 15-20).

With regard to claim 34, Zawacki discloses that the catheter assembly 10 comprises a hollow hub 40 that connects to the assembly (see FIG 1, column 3, lines 48-67). Zawacki further discloses that the inner lumen—which may act as either the venous lumen or arterial lumen, depending on the operation of the catheter (see column 4, lines 5-18)—is removable and replaceable (see column 1, lines 61-67).

With regard to claim 35, Zawacki discloses that the catheter may be inserted into one of the large central veins, which may include a jugular or subclavian vein (see column 2 line 65 to column 3, line 22).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 3-5, 12-14, 21-23, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki.

In the specification and figures, Zawacki discloses the device substantially as claimed by applicant (see rejection above) with the exception of the length of extension of the inner lumen of the catheter with respect to the end of the outer lumen. With regard to claims 3-5, 12-14, 21-23, Zawacki discloses that the inner lumen 30 of catheter 10 is slideable, or adjustable with respect to the distal end of the outer lumen 20 (see column 4, lines 1-18, FIGS 2, 3). Zawacki teaches that the ability to alter the position of the distal end of the inner tube with respect to the outer tube is especially useful in order to relieve blockages in flow. Zawacki's disclosure suggests that the catheter 10 and its lumens 20, 30, are capable of being deployed at the distances claimed by applicant in order to provide for efficient fluid movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the catheter disclosed by Zawacki with the distal ends of the lumens separated by the distance claimed by applicant, in order to provide flexibility in blockage alleviation, as taught by Zawacki.

With regard to claims 32 and 33, Zawacki discloses the method substantially as claimed by applicant with the exception of deploying the catheter in the claimed location and threading the catheter over a guidewire. However, Zawacki specifically discloses that the catheter may be introduced so that the catheter lies at the junction of the superior vena cava and the right atrium and that the position of the inner and outer lumens may be adjusted to provide for the correct location of the lumens within the vasculature (see column 3, lines 7-67). Therefore, it would have been obvious to place the lumens of the catheter disclosed by Zawacki in the locations claimed by applicant, since Zawacki suggests such positioning and teaches that the catheter is adjustable. With regard to the guidewire, Zawacki discloses that the catheter may be provided with a guidewire, indicating that in some applications, the catheter is deployed over a guidewire into the correct position (see column 3, lines 7-22). Therefore, it would have been obvious to deploy the catheter disclosed by Zawacki over a guidewire as claimed by applicant, since Zawacki teaches that the catheter may be supplied with a guidewire for deployment.

6. Claims 6-7, 15-16, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki in view of US 6,595,966 to Davey et al.

In the specification and figures, Zawacki discloses the device substantially as claimed by applicant (see rejection above) with the exception of a tapered distal end of the lumens and a therapeutic agent.

With regard to claims 6-7 and 15-16, Davey discloses a catheter that tapers from proximal end 11 to distal end 15 (see FIG 1A, column 6, lines 37-40). Davey teaches

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that the design may apply to multilumen catheters and minimizes the pressure drop across the catheter, maximizing flow rate through the catheter and minimizing trauma to the fluid flowing through it (see column 4, lines 43-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the dual-lumen catheter disclosed by Zawacki with lumens tapering towards the distal end as disclosed by Davey in order to maximize fluid flow while minimizing fluid trauma, as taught by Davey.

With regard to claim 26, Davey discloses that a surface of the conduit may be treated with heparin, an anticoagulant, in order to prohibit deposit of materials on the surface of the conduit (see column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter disclosed by Zawacki with a therapeutic agent such as an anticoagulant as disclosed by Davey in order to prevent deposit of materials on the surface of the conduit, as taught by Davey.

7. Claims 9, 10, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki in view of US 5,762,631 to Klein.

In the specification and figures, Zawacki discloses the device substantially as claimed by applicant (see rejection above) with the exception of ridge spoke attached between the outer and inner lumens. Examiner considers the ridge and the spoke claimed by applicant to be substantially similar, since all the limitations of the claimed spoke are part of the claimed ridge (that is, a ridge may function as a spoke). Klein discloses a coaxial dual-lumen catheter with elongate protrusions 25, 31, that are

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attached on the inner surface of the outer catheter or the outer surface of the inner catheter, respectively (see FIGS 3A, 3B, column 8, lines 17-24). The ridges or spokes assist in the positioning of the catheters relative to one another after deployment (see column 1, lines 50-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter disclosed by Zawacki with the ridges or spokes disclosed by Klein in order to position the catheters relative to one another, as taught by Klein.

8. Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki in view of US 5,683,640 to Miller et al.

In the specification and figures, Zawacki discloses the device substantially as claimed by applicant (see rejection above) with the exception of fusing the inner and outer lumens together.

Zawacki teaches that the slideable lumens of the catheter 10 may be locked into position by a mechanism at the proximal end of the catheter, but does not teach such a locking at the distal end (see column 6, lines 1-60). Miller teaches a dual-lumen coaxial catheter for dialysis that is formed in one single piece in order to provide a smooth surface that reduces clots and a unitary structure that reduces tip breakage (see column 2, lines 33-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to fuse the lumens disclosed by Zawacki into a single piece, as disclosed by Miller, in order to provide a smooth surface with reduced tip breakage, as taught by Miller.

Response to Arguments

9. Applicant's arguments filed 25 January 2007 have been entered and fully considered.
10. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.
11. Applicant argues that the Fleming device does not anticipate the claims as amended, and that none of the secondary references cure the deficiencies of Fleming. Based on applicant's amendment and arguments, examiner has made a new rejection over US 6,758,836 to Zawacki, as presented above.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

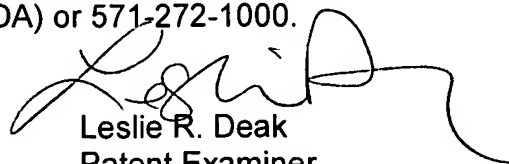
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
20 March 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

